## REMARKS/ARGUMENTS

Claims 33-35, 39, 62, 63 and 71-106 are pending. Reconsideration and allowance in view of the following remarks are respectfully requested.

The amendment filed November 20, 2007 was objected to under 37 C.F.R. §1.57(a). The objection is respectfully traversed.

It is respectfully submitted that the objection under 37 C.F.R. §1.57(a) is improper as the amendment filed November 20, 2007 did not add inadvertently omitted portions of a prior-filed application. The amendments to the specification and drawings filed with the November 20, 2007 response are not material contained in a prior-filed application which Applicant incorporated by reference. As discussed in more detail below, the amendments to the specification and drawings filed November 20, 2007 are permissible amendments to the specification and drawings.

Furthermore, as also discussed in more detail below, the amendments to the specification and drawings filed November 20, 2007 do not incorporate new matter into either the specification or drawings.

Reconsideration and withdrawal of the objections under 37 C.F.R. §1.57(a) are respectfully requested.

Claims 71-106 were rejected under 35 U.S.C. §112, first paragraph. The rejection is respectfully traversed.

The Office Action on page 4, paragraph 7, alleges that claims 71-106 fail to comply with the written description requirement. The Office Action also alleges that the amendment filed November 20, 2007 introduces new matter into the disclosure of the application after its filing date. The Office Action further states that the amendment filed November 20, 2007 discloses

GUNARATNAM et al. Appl. No. 10/090,173

April 8, 2008

additional elements that do not reasonably convey to one of ordinary skill in the art knowledge or how to make and use the claimed invention based upon the original disclosure as filed. The Office Action on page 4, paragraph 7, also notes that claims 71-106 have not been further treated on the merits

Firstly, it is respectfully noted that the Office Action's failure to treat claims 71-106 on the merits is improper under several sections of the MPEP. For example, MPEP \$707.07(g) states:

On the other hand, a rejection on the grounds of *res judicata*, no *prima facie* showing for reissue, <u>new matter</u>, or inoperativeness (not involving perpetual motion) should be accompanied by rejection on all other available grounds. (Underlining emphasis added.)

As another example, MPEP §2143.03 states:

When evaluating claims for obviousness under 35 U.S.C. 103, all the limitations of the claims must be considered and given weight, including limitations which do not find support in the specification as originally filed (i.e., new matter).

As a further example, MPEP §2163.06 states:

The examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by applicant.

Secondly, it is respectfully noted that MPEP §2163.04 states:

The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

MPEP §2163.02 states:

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow GUNARATNAM et al. Appl. No. 10/090,173 April 8, 2008

persons of ordinary skill in the art to recognize that he or she invented what is claimed "

MPEP §2163.02 further states:

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Furthermore, MPEP §2163.02 also states:

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. (Underlining emphasis added.)

It is respectfully submitted the Examiner has not met the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in Applicants' disclosure a description of the invention defined in claims 71-106. The features recited in claims 71-106 were clearly shown in the drawings of the application as originally filed, including as originally filed in parent application 09/504,220, filed February 15, 2000. Furthermore, MPEP \$2163.06 states:

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. <a href="Stated">Stated</a> another way, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter. (Underlining emphasis added.)

supported by the application as originally filed. The arcuate projection 615, shown in Figs.

6b-6d, of the instant application was clearly included in the drawings as originally filed and thus

The amendments to the specification and drawings filed November 20, 2007 are clearly

Applicant was clearly in possession of this claimed feature as of the filing date of the instant application. Similarly, the arcuate ridge 675, shown in Figs. 6a and 6b, of the instant application, was clearly included in the drawings as of the filing date of the instant application. Again, clearly Applicant had possession of this claimed feature as of the filing date of the instant application.

With respect to the conclusion on page 4, paragraph 7, of the Office Action that 
"Applicants amendments to the specification and the drawings disclose additional elements that 
do not reasonably convey to one of ordinary skill in the art knowledge of how to make and use 
the claimed invention based upon the original disclosure as filed," as the claims are not rejected 
as being non-enabled, no further traversal of this statement is deemed necessary except to say 
that it is respectfully noted that the Examiner has not met the initial burden for presenting a 
prima facie case on non-enablement, as required by MPEP \$2164.04.

Reconsideration and withdrawal of the rejection of claims 71-106 under 35 U.S.C. §112, first paragraph are respectfully requested.

Claims 39, 62 and 63 were rejected under 35 U.S.C. §103(a) over Rudolph (U.S. Patent 6,192,886). The rejection is respectfully traversed.

The Office Action on page 5, paragraph 9, acknowledges that Rudolph "does not expressly disclose the first connector portion to be a female connector and a second connector portion to be a male connector." The Office Action on page 5, paragraph 9 concludes, "however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first connector to be female and attached to the mask and the second connector to be male and attached to the strap, since it has been held that rearranging parts of an invention

April 8, 2008

involves only routine skill in the art." The Office Action then cites In re Japikse, 181 F.2d 1019, 86 USPO 70 (CCPA 1950).

It is respectfully noted that MPEP §707.07(f) states:

Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

It is respectfully noted that the undersigned provided a detailed traversal of the rejection of claims 39, 62 and 63, in particular the Examiner's reliance on the court's rationale in <u>In re Japikse</u>, on pages 19-20 of the response filed November 20, 2007. It is also respectfully noted that the Examiner has not provided any answer to undersigned's arguments. The Office Action on page 6, lines 1-2, states that one of ordinary skill in the art would not expect the rearrangement of the parts of Rudolph to adversely affect the effective of the mask to be secured to the patient for operation. However, it is respectfully noted that on page 20, lines 5-16, of the response filed November 20, 2007, the undersigned provided a detailed explanation of how the alleged modification of Rudolph would adversely affect the operation of the nasal mask of Rudolph and why one of ordinary skill in the art would not make the modification suggested in the Office Action. It is respectfully noted that the Examiner has not provided any response to these arguments either.

Reconsideration and withdrawal of the rejection of claims 39, 62 and 63 under 35 U.S.C. \$103(a) over Rudolph are respectfully requested.

Claims 33-35 were rejected under 35 U.S.C. §103(a) over Rudolph in view of Ferrero et al. (U.S. Patent 5.657.493). The rejection is respectfully traversed.

The Office Action on page 7, paragraph 11, alleges that Applicants' arguments filed November 20, 2007 have been fully considered but are not persuasive and that Applicants' arguments fail to comply with 37 C.F.R. §1.111(b) "because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references." The undersigned respectfully disagrees.

It is respectfully submitted that the undersigned provided detailed arguments as to the failure of the combination of Rudolph and Ferrero et al. to establish a prima facie case of obviousness against claims 33-35. For example, on page 22, line 11 through page 23, line 2, the undersigned noted the failure of Rudolph to disclose or suggest 1) a male connector portion including a trailing portion that has a pair of spaced side portions and a crossbar extending transversely therebetween; 2) a male connector portion including a leading portion that has a pair of longitudinally extending side beams spaced slightly inwardly from the side portions, the leading portion including a crosspiece extending between the side beams and defining a leading edge of the male connector portion; 3) a male connector portion having a leading portion also including a cantilevered member extending from an intermediate portion of the crosspiece toward the trailing portion of the male connector portion, the cantilevered member being movable between deflected and undeflected positions and being resiliently biased toward the undeflected position, the cantilevered member including a locking element extending outwardly therefrom, the locking element being positioned on the cantilevered member generally spaced from the crosspiece; and 4) a leading portion of a male connector portion including a ridge structure adjacent the trailing portion and extending generally perpendicularly relative to the side beams.

It is respectfully noted that the Examiner has not provided any answer to the substance of these arguments, as required by MPEP \$707.07(f).

The undersigned also provided detailed arguments on the failure of Ferrero et al. to cure the deficiencies discussed above with respect to Rudolph. For example, on page 23, lines 3-19, of the response filed November 20, 2007, the undersigned noted that the so-called leading end of Ferrero et al. does not include a crosspiece from which a cantilevered member extends. The undersigned also noted that the strap retaining portion 36 of the first coupling portion 30 of Ferrero et al. does not correspond to the cantilevered member of claim 33. The undersigned further noted that there is no disclosure or suggestion by Ferrero et al. that the strap retaining portion is movable between deflected and undeflected positions and is resiliently biased toward the undeflected position. As was noted by the undersigned, the strap retaining portion 36 of Ferrero et al. does not extend from an intermediate portion of a cross piece extending between the side beams.

The undersigned also noted on page 23, lines 14-19, of the November 20, 2007 response that the keeper tooth 58 of Ferrero et al. does not correspond to the locking element of claim 33 because the keeper tooth 58 of Ferrero et al. is not positioned on a cantilevered member generally spaced from a crosspiece that extends between sidebeams.

It is respectfully noted that the Examiner has not provided any response to these arguments, as required by MPEP §707.07(f).

The Office Action on page 7, paragraph 11, further alleges that "Applicant has not provided the Examiner with any proof or reasoning as to how or why the arrangement of the male and female connectors from the mask region to the strap region would inhibit the operation and ability of the airflow mask to properly function." The undersigned respectfully disagrees.

As discussed above, the undersigned on page 20, lines 5-16, of the November 20, 2007 response clearly argued that the formation of the strap securement buttons 90 on the nasal cup 13

April 8, 2008

is necessary for Rudolph to achieve the objective of a flexible nasal cup. The undersigned further argued that one of ordinary in the art would have no reason to change the male connectors (buttons 90) formed on the nasal cup 13 to female connectors, as is proposed in the Office Action, and that the changing of the male connectors (buttons 90) of Rudolph to female connectors would clearly modify the operation of the mask of Rudolph. It is respectfully noted that the Examiner has not provided any answer to these arguments, as is required by MPEP section 707.07(f).

Reconsideration and withdrawal of the rejection of claims 33-35 under 35 U.S.C. §103(a) over Rudolph in view of Ferrero et al. are respectfully requested.

With respect to the citation of Lane (U.S. Patent 5,555,569), the undersigned respectfully notes that MPEP \\$706.02(j) states:

Where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection.

As the Lane reference has not been applied against the claims in a rejection with any specificity, no comments regarding its applicability to the claimed invention are deemed necessary at this time.

In view of the above remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

GUNARATNAM et al. Appl. No. 10/090,173 April 8, 2008

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /John P. Darling/ John P. Darling Reg. No. 44,482

JPD:tlm 901 North Glebe Road, 11th Floor Arlington, VA 22203-1808 Telephone: (703) 816-4000 Facsimile: (703) 816-4100